DOCKET # 02N-0115

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**Statement of William A. Zellmer, Deputy Executive Vice President American Society of Health-System Pharmacists, Before the Food and Drug Administration's Public Hearing on the Agency's Approach to Risk Management of Prescription Drugs, May 22, 2002**

Members of the Committees: My name is William A. Zellmer, and I am the Deputy Executive Vice President of the American Society of Health-System Pharmacists (ASHP). ASHP is the 31,000-member national professional and scientific association that represents pharmacists who practice in hospitals (including outpatient services), health maintenance organizations, long-term care facilities, home care agencies, and other components of organized health care systems. We are grateful to the FDA for calling this public hearing to receive input on the agency's approach to risk management of prescription drugs.

ASHP has a long-standing commitment to helping pharmacists help patients manage the risks inherent in prescription and nonprescription medication use, and we recognize that the FDA has the same commitment, particularly in regard to newer, higher risk drugs. Unfortunately, many of the risk-management plans that have been implemented in recent years fall short of what is needed to manage risk. They fall short because they lack the proper collaborative patient care efforts of all health care providers who are involved in the medication use process.

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ASHP intends to provide more extensive, written comments on the FDA's approach to risk management by the June 21 deadline. Today I would like to discuss a couple of important points.

First and foremost, there needs to be a fundamental reform in prescription drug labeling. Current package inserts and "dear health professional" letters are not adequate. Current labeling does not present information on a drug's safety, efficacy, or risks vs. benefits that is oriented toward a practice environment. ASHP suggests that the FDA, in consultation with health care practitioners, develop, as adjunct labeling for high risk drugs, a core protocol that progresses from diagnostic workups to prescribing decisions based on the interpretation of those workups. Adherence to such a protocol would help influence practitioners' decisions to prescribe or not prescribe medications, based on patient selection criteria and interaction liabilities of one medication with other drugs or disease states. This type of protocol would include proper patient counseling and provision of written patient information.

ASHP believes that the development of this new paradigm is imperative for an appropriate patient care process in all settings -- and for all health care providers -- to ensure appropriate patient selection, appropriate prescribing, and appropriate patient monitoring. Currently, physicians and pharmacists often are not systematically dealing with patients because they are not coming from the same basis of information. A standardized protocol, as we envision it, is a viable tool for drug risk management. It

could be the basis for a collaborative drug therapy management relationship between prescribers and pharmacists that is clearly in the best interest of patients.

The second point that we would like to make relates to restricted drug distribution systems, one of the "tools" that the FDA has been relying on more and more frequently to manage the risk of new drugs. Increased reliance on restricted, closed, or limited drug distribution systems for new, high-risk drugs is a growing concern among ASHP's members. These systems often exclude individual hospital as well as community pharmacies from distributing medications directly to patients. While a number of drugs have been relegated to restricted drug distribution systems, neither the FDA nor drug manufacturers have come forward with information on how well these systems work.

Pharmacists are responsible for ensuring that medications are readily available for patients who need them and that these medications are being used properly. Disruptions and non-standardized distribution processes create procedural confusion for pharmacy and other hospital staff and increase the potential for mistakes. Any restricted distribution or special handling procedure that disrupts that central oversight role of pharmacists represents an interruption in standard medication-use policies and procedures in the health-system setting.

In November of 2000, and again in January of this year, ASHP has drawn the FDA's attention to this issue. We have suggested that when a manufacturer implements a restricted distribution of a drug product, the FDA should obligate the company to ensure

that a patient's usual pharmacist relationship is not disrupted. ASHP also recommended that, if a restricted distribution system is being considered by the FDA as a condition for marketing approval, practicing pharmacists and professional pharmacist societies should be consulted before any restricted distribution requirements are imposed on the product. Open hearings, at which pharmacists can express their views concerning the design of such a system and the impact those systems may have on the safety and effectiveness of patient care, may be one mechanism to accomplish this.

Pharmacists must lead, balance, and manage all the considerations (including safety considerations) about drug distribution. Any distribution process that bypasses pharmacist control or requires exceptional procedures in such settings would be contrary to the best interest of patients. ASHP's members recognize that, despite this general principle and goal of standardization, some exceptions will inevitably have to be made in a patient's best interests. An important point, however, is that these should truly be extraordinary exceptions. The prospect of multiple, unique restrictive drug distribution systems is a frightening picture for pharmacists. Deviations that are unique and that greatly differ from standard practices create obstacles in delivering and administering medications safely.

The patient-pharmacist relationship should not be misinterpreted as merely a product distribution function. The pharmacist's minimum responsibility is to assess the overall appropriateness of all medications with regard to purpose, dosage, and drug/food interactions; patient education and counseling; and adherence or compliance. Patient-

pharmacist relationships in which this level of care is achieved depend on mutual trust, the pharmacist's thorough awareness of the patient's overall medication use, and the pharmacist's actions to ensure the timely supply of drug products. Restricted distribution systems that limit the pharmacist's ability to develop these relationships are disruptive. Restricted drug distribution systems that involve physician-to-patient delivery prevent pharmacists from providing medication appropriateness, dosage and interaction checks, patient education and counseling, monitoring, and follow-up evaluation.

Thoughtful consideration needs to be given to the fact that some of these medications may be initiated or continued for hospitalized patients. Hospital pharmacies may not be able to acquire these medications in a timely manner. This has an adverse effect on patient care and cost. Restricted distribution systems make it difficult for hospital pharmacies to acquire these drugs through their normal supplier channels. This pulls resources from hospital systems that are already stressed.

ASHP believes that, rather than unique drug product distribution schemes, the FDA, in consultation with stakeholders including pharmacists, should develop models for managing patients for whom any high-risk drug product might be indicated and prescribed that incorporate core protocols. These models should focus on requirements for ensuring appropriate use and monitoring, such as patient work-up and selection, provider and patient education, and patient monitoring. Such a system could answer a number of our concerns about important issues such as uniformity of procedures for

patient selection, what kind of distribution systems are most supportive of continuity of care, and what kinds of approaches serve best for provider and patient education.